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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/009,663 | 02/08/2002 | Colin Dunlop | GRIHAC P38AUS | 8376 |

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DAVIS & BUJOLD, P.L.L.C.
FOURTH FLOOR
500 N. COMMERCIAL STREET
MANCHESTER, NH 03101-1151

EXAMINER

FOREMAN, JONATHAN M

| | |
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| ART UNIT | PAPER NUMBER |
|----------|--------------|

3736

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,663

Applicant(s)

DUNLOP, COLIN

Examiner

Jonathan ML Foreman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 47-76, 78, 79, 84, 86, 88, 89 and 93-100 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 47-60, 62-74, 76, 78, 79, 84, 86, 88, 89 and 93-100 is/are rejected.
- 7) ☒ Claim(s) 61 and 75 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/18/05 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claim 89 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 89 is indefinite in that it is directed to a device although it depends from a method claim. Therefore, the scope of the claim is unable to be ascertained. For the purposes of this action it is assumed that claim 89 depends from claim 62.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 47, 48, 51, 52, 57 - 60, 62, 63, 66 - 70, 72, 74, 78, 79, 84, 88, 89 and 93 - 99 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,502,490 to Evans et al.

In regards to claims 78, 79, 96 and 97 Evans et al. discloses a method of monitoring a patient including providing a sensor arrangement which is arranged to detect bodily motion (Col. 6, lines 40 - 44) of the patient and to produce a motion signal in response to motion of the patient (Col. 7, lines 6 - 10), and analyzing the motion signal to determine whether or not the patient is displaying signs of painfulness (Abstract). Evans et al. discloses controlling a peripheral device in response to the analysis (Col. 8, lines 28 - 30). Evans et al. discloses tracking the rate of motion over time and applying trend analysis (Col. 7, line 25 - Col. 8, line 8).

In regards to claims 84, 98 and 99, Evans et al. discloses a device comprising a sensor arrangement for detecting bodily motion of a patient (Col. 6, lines 40 - 44) and to produce a motion signal in response to motion (Col. 6, lines 40 - 44), and a control means (Col. 9, lines 1 - 3) arranged to process the motion signals and analyze the motion signal to determine if the patient is displaying signs of painfulness (Col. 7, line 25 - Col. 8, line 8). Evans et al. discloses controlling a peripheral device (Col. 8, lines 28 - 30). Evans et al. discloses a graphical output which indicates the rate of motion over a time period (Col. 7, lines 56 - 60).

In regards to claims 47, 48, 51, 52, 57, 58, 59, 60, 62, 63, 66 - 70, 72, 74, 88, 89 and 93 - 95, Evans et al. discloses an apparatus and method for monitoring a patient under medical care including providing a sensor arrangement (Col. 6, lines 40 - 44) which is arranged to detect motion of a patient, monitoring the motion signal (Col. 6, lines 40 - 44), analyzing the motion signal to determine whether the motion is motion indicative of patient arousal (Col. 9, lines 1 - 3; Col. 7, line 25 - Col. 8, line 8), and providing an alarm should the monitored motion be indicative of patient

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arousal (Col. 8, lines 62 – 63). Evans et al. discloses providing an alarm should the motion of the patient cease to be detected or fall below a predetermined value (Col. 8, lines 62 – 63). Evans et al. discloses assessing a baseline motion rate which corresponds to the motion rate of the patient at the time the baseline assessment is made (Col. 9, lines 11 – 32), and setting the threshold at a rate above the baseline level. Evans et al. discloses controlling a peripheral device (Col. 8, lines 28 – 30).

6. Claims 62, 63, 65, 68 - 70, 72, 74 and 76 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,410,297 to Joseph et al.

In reference to claims 62, 63, 65, 68 - 70, 72, 74 and 76, Joseph et al. discloses a device for monitoring a human animal patient under medical care including a sensor arrangement to detect bodily motion of the patient and produce a motion signal in response to motion of the patient (Col. 5, lines 39 – 45), a control means (48) to process and analyze signals received from the sensor arrangement to determine if the motion is indicative of patient arousal from a medical procedure involving sedation, and to provide an alarm (Col. 8, lines 35 – 37) should the detected motion be indicative of patient arousal (Col. 8, lines 23 – 34). The sensor arrangement includes a pad on which the patient lies (Col. 3, lines 3 – 7). Joseph et al. discloses assessing a baseline motion rate and setting the threshold above the baseline level (Col. 4, lines 2 – 11). An input means is provided that enables the predetermined level to be set (Col. 8, lines 48 – 54). A recitation with respect to the manner in which an apparatus is intended to be employed (i.e. mounted in a cage) does not impose any structural limitation upon the claimed apparatus that differentiates it from a prior art reference disclosing the structural limitations of the claim. *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1947); *In re Yanush*, 477 F.2d 958, 177 USPQ 705 (CCPA 1973); *In re Finsterwalder*, 436 F.2d 1028, 168 USPQ 530 (CCPA 1971); *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); *In re Otto*, 312 F.2d 937, 136 USPQ 458 (CCPA 1963); *Ex parte Masham*, 2 USPQ2d 1647 (BbPatApp & Inter 1987).

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7. Claim 100 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 3,911,899 to Hattes.

In regards to claim 100, Hattes discloses a method of monitoring a patient under medical care comprising placing a first and second electrode on opposed sides of the patients chest to detect motion of a chest wall of the patient (Col. 4, lines 55 – 59); producing a signal each time a distance between the first and second electrode increases and decreases indicating the motion of the chest wall of the patient (Col. 4, line 64 – Col. 5, line 2); determining a baseline rate of the signals depending on a frequency of the signals produced (Col. 12, lines 31 – 34); providing one of an audio or visual alarm when a subsequent signal is determined to be outside a baseline rate range (Col. 5, lines 23 – 26).

8. Claims 78, 79, 84, 96 and 98 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,233,472 to Bennett et al.

In regards to claims 78, 79, 84, 96 and 98, Bennett et al. discloses a device and method of monitoring a patient under medical care including providing a sensor arrangement (10) that detects bodily motion of the patient (Col. 7, line 20) and produce a motion signal in response to the motion of the patient, analyzing the motion signal in response to bodily motion of the patient to determine whether or not the patient is displaying signs of painfulness (Col. 12, lines 21 – 26). Bennett et al. discloses tracking the rate of motion over a period of time (Col. 15, lines 25 – 41).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary

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skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 47, 48, 50 – 52, 57 – 60, 62, 63, 65 – 70, 72, 74, 88 and 93 – 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,233,472 to Bennett et al. in view of U.S. Patent No. 6,807,965 to Hickie.

In regards to claims 47, 48, 50 – 52, 57 – 60, 62, 63, 65 – 70, 72, 74, 88 and 93 – 95, Bennett et al. discloses a method and device for monitoring an animal human patient under medical care including a sensor arrangement (10) for detecting motion (Col. 7, lines 19 – 20) of the patient, and a control means to process signals received from the sensor arrangement to determine whether the detected motion is indicative of patient arousal from a medical procedure involving sedation (Col. 5, line 42 – 43; Col. 13, line 67 – Col. 14, line 37) . The sensor arrangement includes a pad on which a patient can lie (Col. 5, lines 55 – 59), the pad mounting a sensor for monitoring motion of the patient. Bennett et al. discloses setting a baseline motion rate and monitoring for an increase in rate of motion of the patient over the baseline (Col. 12, lines 15 – 26). Bennett et al. discloses that when a display demonstrating an unacceptably high level of patient motion (i.e. arousal of patient from the medical procedure), or no motion, the operator must take corrective action such as provide more anesthesia to the patient or reduce the amount of anesthesia provided (Col. 15, lines 41 – 44). However, Bennett et al. fails to disclose providing an alarm when an unacceptably high level or no motion is monitored. However, Hickie discloses an apparatus for providing anesthesia to a patient. Hickie discloses the device controlling a peripheral device and having an alarm responsive to patient physiological conditions. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and device as disclosed by Bennett et al. to include means for controlling a peripheral device and having an alarm as taught by Hickie in order to create a closed-loop system to provide anesthesia to a patient while taking into account the

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physiological condition of the patient (Col. 7, lines 3 – 10) and to alert the operator of any abnormal or unsafe operating state of the system (Col. 29 – 34).

11. Claims 49 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,233,472 to Bennett et al. in view of U.S. Patent No. 6,807,965 to Hickle as applied to claims 48 and 63 above, and further in view of U.S. Patent No. 3,911,899 to Hattes.

In regards to claims 49 and 64, Bennett et al. in view of Hickle fails to disclose monitoring the respiratory motion of the patient and providing an alarm when the motion increases beyond a predetermined threshold. Hattes discloses a device and method for monitoring a patient under medical care (Col. 1, line 14) where respiratory motion of a patient is monitored and an alarm is provided when motion increased beyond a predetermined threshold (Col. 1, line 15 – 16; Col. 2, lines 53 – 56). It would have been obvious to one having ordinary skill in the art to modify the method and device as disclosed by Bennett et al. in view of Hickle to monitor the respiratory motion of a patient and provide an alarm as taught by Hattes in order to alert a caregiver so assistance can be given to the patient in order to prevent death or permanent damage to the patient (Col. 1, lines 20 – 23).

12. Claims 81 and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,233,472 to Bennett et al. as applied to claims 96 and 98 above, and further in view of U.S. Patent No. 3,911,899 to Hattes.

In regards to claims 81 and 86, Bennett et al. fails to disclose monitoring the respiratory motion of the patient. However, Hattes discloses a device and method for monitoring a patient under medical care (Col. 1, line 14) where respiratory motion of a patient is monitored (Col. 2, lines 16 – 22). It would have been obvious to one having ordinary skill in the art to modify the method as disclosed by Bennett et al. to monitor the respiratory motion of a patient as taught by Hattes in

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order to monitor irregularities or abnormalities in breathing of the subjects so as to give immediate assistance when needed to prevent death or permanent damage to the patient (Col. 1, lines 11 – 23).

13. Claims 53 – 56 and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,233,472 to Bennett et al. in view of U.S. Patent No. 6,807,965 to Hickle as applied to claims 47 and 62 above, and further in view of and further in view of U.S. Patent No. 4,969,459 to Gusakov.

Gusakov discloses monitoring a patient under medical care having a control means arranged to receive input from a temperature sensor proximate a patient sensing the body temperature of a patient and to provide an alarm if the temperature goes above or below a predetermined threshold (Col. 2, line 43 – Col. 3, line 10). It would have been obvious to one having ordinary skill in the art to modify the method and device as disclosed by Bennett et al. in view of Hickle. to include the capabilities of temperature monitoring and alarm notification as taught by Gusakov in order to alert a caregiver that a patient's body temperature is no longer in a normal range.

14. Claims 97 and 99 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,233,472 to Bennett et al. as applied to claims 96 and 98 above, and further in view of U.S. Patent No. 6,807,965 to Hickle

In regards to claims 97 and 99, Bennett et al. discloses a device and method for use in monitoring a patient under anesthesia, but fails to disclose controlling operation of a peripheral device. Hickle discloses a device for use in monitoring a patient under anesthesia and discloses the device controlling a peripheral device in response to measured physiological parameters of the patient (Abstract). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device and method as disclosed by Bennett et al. to include capabilities for controlling the operation of a peripheral device in order to create a closed-loop

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system to provide anesthesia to a patient while taking into account the physiological condition of the patient (Col. 7, lines 3 – 10).

Response to Arguments

15. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The claims merely recite analyzing the motion signal. This analysis need not be complex. Each of the applied cited references disclose a sensor arrangement that creates a motion signal in that a current or voltage is generated that is analyzed by a processor. In regards to Hattes, Applicant did not expand on why Hattes is not believed to teach, suggest or disclose all features of the claimed invention.

Allowable Subject Matter

16. Claims 61 and 75 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the

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THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

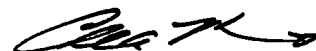
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703) 305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703)308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JMLF



**CHARLES MARMOR
PRIMARY EXAMINER**